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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/075,593	02/15/2002	Ellen M. Heath	GISM-P01-011	9392

7590 12/11/2006

Ropes & Gray
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Washington, DC 20005

EXAMINER	
STRZELECKA, TERESA E	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/075,593	HEATH ET AL.	
	Examiner	Art Unit	
	Teresa E. Strzelecka	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 September 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9-17,19-28,30-38,40-49,51-59 and 61-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,9-17,19-28,30-38,40-49,51-59 and 61-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This application has been transferred to examiner Teresa Strzelecka in Art Unit 1637 due to examiner's Chunduru temporary absence.

2. This office action is in response to an amendment filed September 19, 2006. Claims 1-7, 9-17, 19-28, 30-38, 40-49, 51-59 and 61-65 were previously pending. Applicants amended claims 2, 9, 19, 20, 30, 40, 41, 51, 61 and 62. Claims 1-7, 9-17, 19-28, 30-38, 40-49, 51-59 and 61-65 are pending and will be examined.

3. Applicants' amendments overcame the rejection of claims 2-7, 9-17, 19-23, 30-33, 40-44, 51-54 and 61-65 under 35 U.S.C. 112, second paragraph. All other previously presented rejections are maintained for reasons given in the "Response to Arguments" section below.

4. Applicants' amendment to the specification obviated the objection presented in the previous office action.

Response to Arguments

5. Applicant's arguments filed have been fully considered but they are not persuasive.

A) Regarding the rejection of claims 1, 2, 4, 7, 9-16, 19-24, 28, 30-37 and 40-44 under 35 U.S.C. 102(b) as anticipated by Younghusband et al., Applicants argue that the term "sequential" with respect to method steps does not imply that there are intervening steps between two sequential steps, and Younghusband et al. teach such intervening steps. However, the preamble to claim 1 (and 2) contains the following phrase: "comprising the following sequential steps". As noted in MPEP 2111.3:

2111.03 Transitional Phrases [R-3]

The transitional phrases "comprising", "consisting essentially of" and "consisting of" define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim.

The transitional term "comprising", which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps. See, e.g., >Mars Inc. v. H.J. Heinz Co., 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004) ("like the term 'comprising,' the terms 'containing' and 'mixture' are open-ended.").< Invitrogen Corp. v. Biocrest Mfg., L.P., 327 F.3d 1364, 1368, 66 USPQ2d 1631, 1634 (Fed. Cir. 2003) ("The transition 'comprising' in a method claim indicates that the claim is open-ended and allows for additional steps."); Genentech, Inc. v. Chiron Corp., 112 F.3d 495, 501, 42 USPQ2d 1608, 1613 (Fed. Cir. 1997) ("Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim.); Moleculon Research Corp. v. CBS, Inc., 793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); In re Baxter, 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); Ex parte Davis, 80 USPQ 448, 450 (Bd. App. 1948) ("comprising" leaves "the claim open for the inclusion of unspecified ingredients even in major amounts"). >In Gillette Co. v. Energizer Holdings Inc., 405 F.3d 1367, 1371-73, 74 USPQ2d 1586, 1589-91 (Fed. Cir. 2005), the court held that a claim to "a safety razor blade unit comprising a guard, a cap, and a group of first, second, and third blades" encompasses razors with more than three blades because the transitional phrase "comprising" in the preamble and the phrase "group of" are presumptively open-ended. "The word 'comprising' transitioning from the preamble to the body signals that the entire claim is presumptively open-ended." Id. In contrast, the court noted the phrase "group consisting of" is a closed term, which is often used in claim drafting to signal a "Markush group" that is by its nature

closed. Id. The court also emphasized that reference to "first," "second," and "third" blades in the claim was not used to show a serial or numerical limitation but instead was used to distinguish or identify the various members of the group. Id."

Therefore, the presence of the phrase "comprising" implies that additional steps between the sequential steps are permitted, and thus Younghusband et al. anticipate the claims.

The rejection is maintained.

B) Regarding the rejection of claims 3-6, 17, 25-27, 38, 45-49, 51-59 and 61-65 under 35 U.S.C. 103(a) over Younghusband et al. and Gray et al., Applicants argue that Younghusband et al. do not anticipate the independent claims. This argument was addressed above.

The rejection is maintained.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A.Claims 1-2, 4, 7, 9-16, 19-24, 28, 30-37, 40-44 are rejected under 35 U.S.C. 102(b) as being anticipated by Younghusband et al. (J virolOgy, Vo. 43, No. 2, pp. 705-713, 1982).

With reference to the instant claims 1-2, 24, Younghusband et al. teach a method for isolating DNA from a biological sample comprising cells (cultured Hela cells) wherein Younghusband et al. disclose that the method comprises sequential steps:

(a) separating the biological material comprising DNA from remainder of the biological sample (separating nuclei from the remainder of the cellular components) (see page 706, col. 1, line 1-10 of step (i) under nuclear matrix sub heading),

(b) contacting the separated biological material comprising DNA with a hypertonic, high salt solution (2.0M NaCl-glycerol solution) so as to form a suspension of said biological material containing DNA (see page 706, col. 1, line 10-20 of step (i) under nuclear matrix sub heading);

(c) contacting the suspension with a cell lysis reagent (lysis mixture comprising 3% SDS and 2% β-mercaptoethanol) so as to lyse the biological material containing DNA to form a lysate comprising DNA and non-DNA components (cellular debris) released from the biological material (see page 706, col. 1, line 20-23 of step (i) under nuclear matrix sub heading),

(d) separating DNA from the non-DNA biological components in the lysate of step (c) to yield isolated DNA (see page 706, col. 1, line 23-31 of step (i) under nuclear matrix sub heading).

With regard to claim 4, Younghusband et al. teach that the biological sample comprises a virus (see page 706, col. 1, line 2-4).

With regard to the instant claims 7, 28, Younghusband et al. teach that the non-DNA biological component comprises protein (cellular debris) (see page 707, Fig. 1 legend).

With regard to claims 9-12, 30-33, Younghusband et al. teach that the hypertonic high salt solution comprises sodium salt in an effective amount greater than about 1M and about 2M that can precipitate proteins (see page 706, col. 1, line 10-20 of step (i) under nuclear matrix sub heading, page 707, Fig. 1 legend).

With regard to claims 13-16, 34-37, Younghusband et al. teach that the lysis reagent comprises anionic detergent of sodium salt (SDS), with a concentration greater than 0.1% w/v (see page 706, col. 1, line 20-23 of step (i) under nuclear matrix sub heading).

With regard to claims 19-20, 40-41, Younghusband et al. teach that separating the DNA from lysate comprises precipitating non-DNA biological components from lysate by centrifugation

(see page 706, col. 1, line 20-23 of step (i) under nuclear matrix sub heading, paragraph 2 of step (ii)).

With regard to claim 21, 42, Younghusband et al. also teach isolated DNA is contacted with an alcohol (ethanol) to isolate DNA (see page 706, col. 1, line 20-23 of step (i) under nuclear matrix sub heading).

With regard to claim 22, 43, Younghusband et al. teach that the method further comprises contacting isolated DNA with a wash solution (phenol wash solution) (page 706, col. 1, line 20-23 of step (i) under nuclear matrix sub heading).

With regard to claim 23, 44, Younghusband et al. teach that the isolated DNA is treated with a hydration reagent (Tris EDTA buffer) (see page 706, col. 1, line 20-23 of step (i) under nuclear matrix sub heading). Accordingly Younghusband et al. anticipates the instant claims.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3-6,17, 25-27, 38, 45-49, 51-59, 61-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Younghusband et al. (J virology, Vo. 43, No. 2, pp. 705-713, 1982) in view of Gray et al. (USPN. 5, 777, 098).

Younghusband et al. teach a method for isolating DNA from a biological sample comprising cells (cultured Hela cells) wherein Younghusband et al. disclose that the method comprises sequential steps:

(a) separating the biological material comprising DNA from remainder of the biological sample (separating nuclei from the remainder of the cellular components) (see page 706, col. 1, line 1-10 of step (i) under nuclear matrix sub heading),

(b) contacting the separated biological material comprising DNA with a hypertonic, high salt solution (2.0M NaCl-glycerol solution) so as to form a suspension of said biological material containing DNA (see page 706, col. 1, line 10-20 of step (i) under nuclear matrix sub heading);

(c) contacting the suspension with a cell lysis reagent (lysis mixture comprising 3% SDS and 2% β-mercaptoethanol) so as to lyse the biological material containing DNA to form a lysate comprising DNA and non-DNA components (cellular debris) released from the biological material (see page 706, col. 1, line 20-23 of step (i) under nuclear matrix sub heading),

(d) separating DNA from the non-DNA biological components in the lysate of step (c) to yield isolated DNA (see page 706, col. 1, line 23-31 of step (i) under nuclear matrix sub heading).

With regard to the instant claims 7, 28, Younghusband et al. teach that the non-DNA biological component comprises protein (cellular debris) (see page 707, Fig. 1 legend).

With regard to claims 9-12, 30-33, Younghusband et al. teach that the hypertonic high salt solution comprises sodium salt in an effective amount greater than about 1M and about 2M that can

precipitate proteins (see page 706, col. 1, line 10-20 of step (i) under nuclear matrix sub heading, page 707, Fig. 1 legend).

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With regard to claim 22, 43, Younghusband et al. teach that the method further comprises contacting isolated DNA with a wash solution (phenol wash solution) (page 706, col. 1, line 20-23 of step (i) under nuclear matrix sub heading).

With regard to claim 23, 44, Younghusband et al. teach that the isolated DNA is treated with a hydration reagent (Tris EDTA buffer) (see page 706, col. 1, line 20-23 of step (i) under nuclear matrix sub heading).

Younghusband et al. also teach RNAse treatment of isolated DNA (page 706, col. 1, line 20-23 of step (i) under nuclear matrix sub heading).

However, Younghusband et al. did not teach isolating DNA from blood cells.

Gray et al. teach a method for DNA purification wherein Gray et al. teach that the method comprises (a) separating the biological material comprising DNA from remainder of the biological sample which includes contacting whole blood with a red blood lysis solution and separating white

blood cells comprising DNA (see column 2, lines17-25, column 3, lines 1-21, column 7, lines 1-12); (b) contacting the separated biological material (white blood cells) comprising DNA with a hypertonic high salt solution so as to form a suspension of said biological material containing DNA (see column 4, lines 48-58); (c) contacting the suspension with a cell lysis reagent to release DNA from non-DNA components (see column 4, lines 34-36), (d) separating DNA by centrifugation to yield isolated DNA (see column 5, lines 1-11). Gray et al. also teach that physically separating the DNA from the lysate comprises precipitating DNA with an alcohol, followed by awash solution (see column 5, lines 1-11).

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made, to combine a method of isolating DNA from a biological sample as taught by Younghusband et al. with an additional wash solution step as taught by Gray et al. to achieve expected advantage of developing a enhanced method of extracting purified DNA from various biological samples including blood samples. An ordinary person skill in the art would have a reasonable expectation of success that the modification of the method of Younghusband et al. with various biological sources including blood cells would result in wide use of the method because Gray et al. explicitly taught that "the method provides rapid extraction of substantially pure DNA from any biological sample including blood, plant and animal tissue in less than about 15 minutes" (col. 2, line 57-67) and such modification of the method is considered as obvious over the cited prior art. Further it is noted that selection of parameters such as additional RNAse in lysis reagent for routine optimization are explicitly recognized in Younghusband et al. As noted in In re Aller, 105 USPQ 233 at 235, More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been

presented that the inclusion of RNAse was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

9. No claims are allowed.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Teresa E. Strzelecka whose telephone number is (571) 272-0789. The examiner can normally be reached on M-F (8:30-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Teresa E Strzelecka
Primary Examiner
Art Unit 1637
Teresa Strzelecka
12/05/06